

Memorandum

To: Board Members

Date: October 22, 2008

From: Anne Sodergren
Board of Pharmacy**Subject: Regulation Hearing – Proposal to Amend 16 CCR §1773 and to Adopt §1773.5**

At this meeting the board will be conducting a regulation hearing to hear testimony about the proposed regulation to specify the criteria for an ethics course, which may be required as part of discipline imposed on a pharmacist for violation of pharmacy law.

In April 2007, the board established a subcommittee to examine the development of an ethics course for pharmacists as an enforcement option as part of discipline. Based on the work of this subcommittee, the subcommittee recommended to the full the board that it vote to create a program similar to the program used by the Medical Board. This proposal would establish in regulation the minimum requirements for the ethics program. These minimum requirements are designed to better guide the board and licensees when they are finding a course and will ensure that the course will be of high quality. This proposal will provide licensees with the necessary information to assist in their rehabilitation.

The board determined the requirements as necessary, based on testimony received during the October 2007 Board Meeting. During the meeting, the board received testimony from the Institute for Medical Quality (IMQ), the course provider for the Medical Board's ethic course. The board determined that a minimum of 14 direct contact hours is appropriate to allow for case presentations, group discussion and experiential exercises and role-playing to ensure sufficient time to discuss and evaluate situations. In addition, based on the recommendation of IMQ, the board's proposal also incorporates an additional 8 hours of time to allow the pharmacist to complete self-reflection on the decisions made that led to the violations and ultimate referral to the program and post-classroom instruction for up to one year. This self-reflection includes completing questions as part of a background assessment. The two post-course longitudinal studies ensure that the pharmacist has successfully internalized the necessary changes to prevent future violations resulting from unethical behavior.

The board received comments on this proposal from John Cronin. His comments are provided in **ATTACHMENT 1**.

In addition, board staff received a suggestion to change the word "medicine" to "pharmacy" under Section 1773.5(a)(5)(B). A copy of the draft language reflecting this change is in **ATTACHMENT 2**. The change is highlighted with double strikethrough and double underline.

During the regulation hearing additional testimony will be provided for board consideration. At the conclusion of the hearing the board may consider revising the language. Any changes to the language will result in either an additional 15-day comment period or a new 45-day comment period depending on the scope of the changes.

Attachment 1

Comments from John Cronin

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October 20, 2008

Karen Cates
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Re: Proposed Regulation Detailing Criteria for Ethics Course

Dear Ms. Cates and Members of the Board of Pharmacy:

These comments are being sent with regard to the the proposed regulation detailing the criteria for any Ethics Course required as an optional condition for probation in disciplinary actions by the Board. I appreciate the opportunity to provide these comments as well as the request by the California Pharmacists Association to have a hearing on this proposed regulation at the upcoming Board meeting.

As the former General Counsel for CPhA and as an attorney who defends pharmacists and other licensees in actions brought by the Board, I have considerable experience with this sort of "enhancement" of Board disciplinary processes. I believe this requirement should be given full consideration before being adopted. Based on my review of the materials and history of this proposal, I do not believe the Board has fully performed its due diligence in drafting and considering this regulation.

The requirement for an ethics course as an optional condition for probation was added when the Board recently considered a revised set of Disciplinary Guidelines which, as of this writing, have not yet been approved by the Office of Administrative Law. [Board of Pharmacy website, checked on October 20, 2008]. The specific language in the Disciplinary Guidelines reads:

40. Ethics Course

Within sixty (60) calendar days of the effective date of this decision, respondent shall enroll in a course in ethics, at respondent's expense, approved in advance by the board or its designee. Failure to initiate the course during the first year of probation, and complete it within the second year of probation, is a violation of probation.

Respondent shall submit a certificate of completion to the board or its designee within five

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days after completing the course.

I have no dispute with the wisdom of including this sort of optional probation term in the Disciplinary Guidelines and I can think of many circumstances where such a requirement would be a beneficial component of discipline. However, as with many things, the difficult part of this type of requirement is in its execution. For the reasons detailed below, I do not believe the specifics of the ethics course requirements in the proposed regulation are appropriate.

Flexibility

The proposed regulation language uses a “one size fits all” approach to the ethics course requirement. I can see no good reason for this. The Board provides no reason why, for example, EVERY violation that will trigger this probation term should require a 22 hour ethics course or why ALL licensees who have this term imposed should be subject to a 6 and 12 month longitudinal follow up. In fact, the appearance drawn from this proposed language, which has essentially been copied from the language adopted by the Medical Board for their ethics course requirement, is that the Board has not given significant consideration to this new probationary term.

Imposing this probation term should not be seen as the same for physicians and pharmacists. Further, the need for an ethics course cannot be identical for the broad spectrum of violations of pharmacy law for which this requirement can be imposed. The specifics of the course cannot be the same for violations of controlled substance law as they are for violations of the unfair trade practices laws. By adopting a fixed and inflexible set of criteria for the ethics course, the Board is compromising the utility of such a course as a tool in discipline. The Board should give more consideration to this proposed approach before adopting any regulation detailing the criteria for ethics courses.

Application

The minutes of the January 2007 Board meeting reflect the presentation made by former Board Executive Office and Medical Board member Lori Rice introducing the idea of an ethics course to the Board of Pharmacy. Ms. Rice’s presentation recounted the experience of the Medical Board in dealing with a similar requirement. She mentioned the distinction between “Standard of Care” violations, where a practitioner makes a mistake, for example, and “Ethics” violations, examples of which were molestation of a patient, drug diversion or Medi-Cal/Medicare fraud. Among the questions she said needed to be addressed by the Board of Pharmacy in considering a requirement for an ethics course were:

1. What type of cases would be referred?
2. What criteria would be needed to assess rehabilitation, redemption and contrition? Is there a willingness to change on the part of the licensee?
3. How to build skills involving empathy, to ensure there is an opportunity to focus about the impact of the licensee’s action on society and how it impacted patients?

As noted above, there is a clear difference in how these factors would be applied to physicians versus pharmacists. In fact, the proposed language, including the language in the Disciplinary Guidelines, gives little indication of what violations or cases would trigger the requirement for this optional term. Based on my experience with current Board practices and the evolution of the Cite

and Fine program, I would expect that this requirement would be imposed more frequently than initially expected, and could easily expand until it becomes a “standard optional” term for probation in disciplinary actions or for abatement in cite and fine cases.

The appropriateness of such broad application calls for additional guidance from the board members as to how and when an ethics course should be required, particularly in light of the other factors Ms. Rice suggested. That is, will a 22 hour ethics course focused on diversion of controlled substances really result in rehabilitation of a licensee who is being disciplined for repeated violations of staffing requirements and whose actions were taken for business profitability purposes? Staffing violations create significant ethical issues tied to patient safety and societal harm, but the ethics course described in the proposed regulation seems ill suited to deal with that problem or a wide range of other issues.

Duration and Content

As argued above, the specifics of ethics violations vary, as do the reasons for those violations. While an ethics course may be an appropriate requirement for rehabilitation, the specifics of that course will be equally varied. The value of that course may depend more on finding alternative ways to deal with the problems that led to the violation rather than with a “baseline assessment . . . to determine . . . knowledge/awareness of ethical and legal issues . . .” [proposed Sec. 1773.5(a)(5)(B)] For some violations, the framework proposed in the regulation for the ethics course will be appropriate and needed. For others, it will not. While the proposed language is vague, it is sufficiently detailed to limit the number of eligible courses that the Board could approve and the number of providers who could develop approvable courses. As I understand it, the Board currently has only one contractor with only a single ethics course under development. This can hardly provide the variety needed for effective implementation of this requirement.

To illustrate this point I have attached a copy of the PACE Program offered at the University of California, San Diego, which satisfies the requirements of the Medical Board’s ethics course program. I ask the Board members to review this syllabus and consider whether this course would meet the needs of wide range of violations for which an ethics course requirement would be appropriate.

A more open approach to approval of courses that are acceptable to meet an ethics course requirement is needed. There is no reason why a properly structured and focused course, regardless of its length, could not satisfy the need for ethical consideration and training to which this requirement is directed. Courses can be developed to address some or all of the violations for which an ethics course is required. These are alternative approaches that I believe will better meet the needs of both the Board and the licensee and in a less monopolistic manner.

Costs

A significant factor that the Board needs to address is the cost for these courses. The discussion at the October 2007 Board meeting reflected that the two day course offered by Institute for Medical Quality to meet the Medical Board’s requirements costs \$1900 per attendee. Additional costs for pharmacists to take time off to attend the course could easily add another \$1000 to the total. Likewise, the 6 month and 12 month follow up sessions could add additional costs. While imposing this level of costs may be acceptable in many circumstances, the Board needs to carefully consider whether the value received by the public from an ethics course as proposed in

this language is worth the imposition of this cost. The alternative is to reconsider this proposal to make sure that the costs paid by licensees as part of the disciplinary process truly provides equivalent benefit to the public.

Recommendation

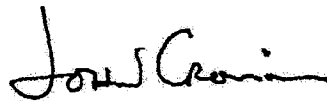
As noted above, these comments are not directed towards whether or not an ethics course is an appropriate part of the disciplinary process. Rather, my comments are directed toward whether the regulation language being considered reflects the most appropriate way to implement such a program. I believe the public, the board and the licensees it regulates would be better served by a program that had much greater flexibility as to the type, content, duration and providers of acceptable ethics courses. This would, of necessity, require more flexibility from the Board on the specifics of the courses that would be approved as part of settlement of disciplinary cases. Such an approach is appropriate because of the wide variety of violations which may trigger a requirement for a licensee to take an ethics course.

I suggest that the Board look into the ethics course requirement further with the goal of doing the following:

1. Identify classes of violations which would trigger a requirement for an ethics course.
2. For each class of violation:
 - a. Identify the types of remediation sought from taking an ethics course.
 - b. Identify the criteria needed to achieve the remediation sought.
3. Identify the sources that are available for providing appropriate ethics courses.
4. Craft regulation language that accommodates the variety of options that result.

I believe this further consideration of this requirement is an essential part of the due diligence that should be performed by the Board before acting on this regulation proposal.

Sincerely,

A handwritten signature in black ink, appearing to read "John A. Cronin". The signature is fluid and cursive, with the first name "John" and last name "Cronin" clearly distinguishable.

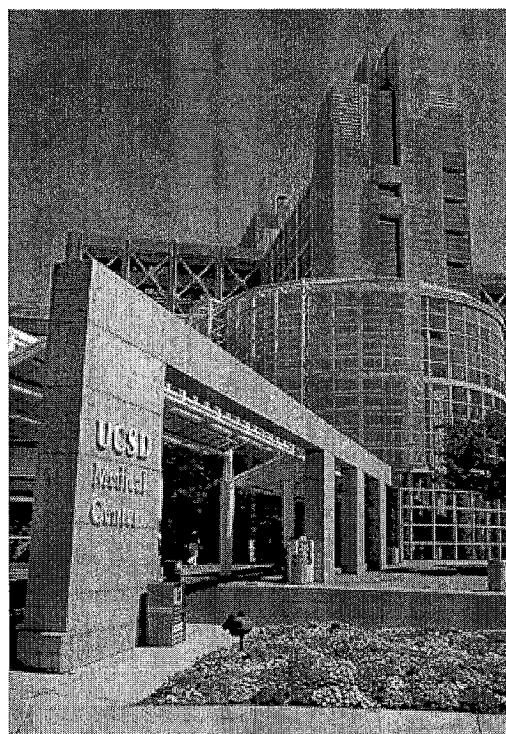
John A. Cronin, Pharm.D., J.D.

This activity is in compliance with California Assembly Bill 1195 which requires continuing medical education activities with patient care components to include curriculum in the subjects of cultural and linguistic competency. Cultural competency is defined as a set of integrated attitudes, knowledge, and skills that enables health care professionals or organizations to care effectively for patients from diverse cultures, groups, and communities. Linguistic competency is defined as the ability of a physician or surgeon to provide patients who do not speak English or who have limited ability to speak English, direct communication in the patient's primary language. Cultural and linguistic competency was incorporated into the planning of this activity. Additional resources on cultural and linguistic competency and information about AB1195 can be found on the UCSD CME website at <http://cme.ucsd.edu>.

University of California, San Diego School of Medicine is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

The University of California, San Diego School of Medicine designates this educational activity for a maximum of 20.5 AMA PRA Category 1 Credits™.

Physicians should only claim credit commensurate with the extent of their participation in the activity.



UCSD PACE Program

UCSD PACE Program
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Phone: (619) 543-6770
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UCSD PACE Program



Physician Prescribing Course

2008 Course Dates

January 28-30

April 21-23

June 2-4

September 8-10

October 27-29

Cost: \$1,800

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Designed for physicians who confront disciplinary actions from licensing boards over drug prescribing issues, or for those physicians who wish to improve their knowledge of drug pharmacology and prescribing issues.

Course objectives covered during this two and one-half day program:

- To improve participants' prescribing practices through education and illustration
- To increase physician knowledge about the laws pertaining to medical prescribing practices
- To summarize the legal, biomedical and clinical aspects of prescribing drugs
- To improve participants' knowledge regarding the law and prescribing controlled substances
- To effectively recognize and manage the 'difficult' patient

This course was designed in response to numerous requests from state medical boards, hospitals, risk management groups and hospital peer review committees to address errors commonly identified in medical prescribing and teach proper prescribing practices.

Monday Course Overview:

- **Welcome and Continental Breakfast**
- **Management of Headache and Back Pain**
David Bazzo, M.D.
- **Principles of Pharmacokinetics and Drug Metabolism**
Lee Cantrell, Pharm. D., DABAT
- **Pharmacology of Sedative Hypnotics**
Lee Cantrell, Pharm. D., DABAT
- **Pharmacology of Methlyphenidates & Amphetamines**
Ed McFeely, B. Pharm
- **Lunch**
- **Drug Interactions**
David Adler, Pharm.D.
- **The Difficult Patient: Questions and Answers**
Gordon McGuire, Pharm. D.
- **Prescribing Laws of California and California Medical Board Guidelines**
Suraj Achar, M.D.
- **Open Book Exam Materials and Instruction**
- **Evening:Independent Study (2.0 hours)**
Open Book Exam

Tuesday Course Overview:

- **Continental Breakfast**
- **Critical Review of the Medical Literature**
David Folsom, M.D.
- **Dealing with the Demanding Patient, the Seductive Patient, and the Manipulative Patient**
Margaret McCahill, M.D.
- **Lunch**
- **Problem Oriented Medical Records and the Medical Board of California's Guidelines on Prescribing for Chronic Pain**
Suraj Achar, M.D.
- **Fibromyalgia**
Suraj Achar, M.D.

Tuesday Course Overview cont'd:

- **Pharmacology: Establishing, Maintaining, and Monitoring Compliance**
Robert Weibert, Pharm. D.
- **Pharmacology of Narcotics**
Robert Weibert, Pharm. D.
- **Non-narcotic Alternatives for Chronic Pain**
Robert Weibert, Pharm. D.
- **Evening:Independent Study (2.0 hours)**
Open Book Exam

Wednesday Course Overview:

- **Continental Breakfast**
- **A. Recipe for Personality Soup: Start with Boundaries, Mix in Sage, and Simmer Gently.**
B. General Case Discussion
Margaret McCahill, M.D.
- **Review of Open Book Examination**
Tyson Ikeda, M.D.
- **Review and Evaluation of Physician Prescribing Course, Post-Test and Course Conclusion**

The University of California, San Diego Continuing Medical Education (UCSD CME) requires that the content of CME activities and related materials provide balance, independence, objectivity, and scientific rigor. Planning must be free of the influence or control of a commercial entity, and promote improvements or quality in healthcare. Faculty participating in UCSD sponsored CME programs are expected to disclose to the activity participants any conflict(s) of interest that may have a direct bearing on the subject matter in their role as planners or presenters. This pertains to relationships with pharmaceutical companies, biomedical device manufacturers, or other corporations whose products or services are related to the course content. UCSD CME has the following mechanisms in place to resolve conflicts of interest 1) altering the financial relationship with the commercial interest, 2) altering the individual's control over CME content about the products or services of the commercial interest, and/or 3) validating the activity content through independent peer review. UCSD CME will resolve all conflicts of interest prior to an educational activity being delivered to learners. Participants will be asked to evaluate whether the speaker's outside interests reflect a possible bias in the planning or presentation of the activity. This information is used to plan future activities.

Attachment 2

Suggested modified language

Board of Pharmacy
Specific Language to Amend Section 1773 and Add Section 1773.5

Amend Section 1773 to Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1773. Disciplinary Conditions of Probation of Pharmacist.

(a) Unless otherwise directed by the Board in its sole discretion, any pharmacist who is serving a period of probation shall comply with the following conditions:

- (1) Obey all laws and regulations substantially related to the practice of Pharmacy;
- (2) Report to the Board or its designee quarterly either in person or in writing as directed; the report shall include the name and address of the probationer's employer. If the final probation report is not made as directed, the period of probation shall be extended until such time as the final report is made;
- (3) Submit to peer review if deemed necessary by the Board;
- (4) Provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the Board;
- (5) Inform all present and prospective employers of license restrictions and terms of probation. Probationers employed by placement agencies must inform all permittees in whose premises they work of license restrictions and terms of probation.
- (6) Not supervise any registered interns nor perform any of the duties of a preceptor;
- (7) The period of probation shall not run during such time that the probationer is engaged in the practice of pharmacy in a jurisdiction other than California.

(b) If ordered by the Board in an administrative action or agreed upon in the stipulated settlement of an administrative action, any registered pharmacist who is serving a period of probation shall comply with any or all of the following conditions;

- (1) Take and pass all or any sections of the pharmacist licensure examination and/or attend continuing education courses in excess of the required number in specific areas of practice if directed by the Board;
- (2) Provide evidence of medical or psychiatric care if the need for such care is indicated by the circumstances leading to the violation and is directed by the Board;
- (3) Allow the Board to obtain samples of blood or urine (at the pharmacist's option) for analysis at the pharmacist's expense, if the need for such a procedure is indicated by the circumstances leading to the violation and is directed by the Board;
- (4) If and as directed by the Board, practice only under the supervision of a pharmacist not on probation to the Board. The supervision directed may be continuous supervision, substantial supervision, partial supervision, or supervision by daily review as deemed necessary by the Board for supervision, partial supervision, or supervision by daily review as deemed necessary by the Board for the protection of the public health and safety.
- (5) Complete an ethics course that meets the requirements of section 1773.5.

(c) When the circumstances of the case so require, the Board may impose conditions of probation in addition to those enumerated herein by the terms of its decision in an administrative case or by stipulation of the parties.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4300, Business and Professions Code.

Add Section 1773.5 to Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1773.5 Ethics Course Required as Condition of Probation.

When directed by the board, a pharmacist or intern pharmacist may be required to complete an ethics course that meets the requirements of this section as a condition of probation, license reinstatement or as abatement for a citation and fine. Board approval must be obtained prior to the commencement of an ethics course.

a. The board will consider for approval an ethics course that at minimum satisfies the following requirements:

- REMOVE ITALICS (1) Duration. The course shall consist of a minimum of 22 hours, of which at least 14 are contact hours and at least 8 additional hours are credited for preparation, evaluation and assessment.
- (2) Faculty. Every instructor shall either possess a valid unrestricted California professional license or otherwise be qualified, by virtue of prior training, education and experience, to teach an ethics or professionalism course at a university or teaching institution.
- (3) Educational Objectives. There are clearly stated educational objectives that can be realistically accomplished within the framework of the course.
- (4) Methods of Instruction. The course shall describe the teaching methods for each component of the program, e.g., lecture, seminar, role-playing, group discussion, video, etc.
- (5) Content. The course shall contain all of the following components:
- (A) A background assessment to familiarize the provider and instructors with the factors that led to the prospective candidate's referral to the class.
 - (B) A baseline assessment of knowledge to determine the participant's knowledge/awareness of ethical and legal issues related to the practice of ~~medicine~~ pharmacy in California, including but not limited to those legal and ethical issues related to the specific case(s) for which the participant has been referred to the program.
 - (C) An assessment of the participant's expectations of the program, recognition of need for change, and commitment to change.
 - (D) Didactic presentation of material related to those areas that were problems for the participants based upon the results of the background assessments and baseline assessments of knowledge.
 - (E) Experiential exercises that allow the participants to practice concepts and newly developed skills they have learned during the didactic section of the class.

- (F) A longitudinal follow-up component that includes (1) a minimum of two contacts at spaced intervals (e.g., 6 months and 12 months) within one year after course completion or prior to completion of the participant's probationary period if probation is less than one year, to assess the participant's status; and (2) a status report submitted to the division within 10 calendar days after the last contact.
- (6) Class Size. A class shall not exceed a maximum of 12 participants.
- (7) Evaluation. The course shall include an evaluation method that documents that educational objectives have been met - e.g. written examination or written evaluation - and that provides for written follow-up evaluation at the conclusion of the longitudinal assessment.
- (8) Records. The course provider shall maintain all records pertaining to the program, including a record of the attendance for each participant, for a minimum of 3 years and shall make those records available for inspection and copying by the board or its designee.
- (9) Course Completion. The provider shall issue a certificate of completion to a participant who has successfully completed the program. The provider shall also notify the board or its designee in writing of its determination that a participant did not successfully complete the program. The provider shall fail a participant who either was not actively involved in the class or demonstrated behavior indicating a lack of insight (e.g., inappropriate comments, projection of blame). This notification shall be made within 10 calendar days of that determination and shall be accompanied by all documents supporting the determination.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4300, Business and Professions Code.